1	MAUREEN E. McCLAIN (State Bar No. 06208	50)
2	Email: mcclain@kmm.com ALEX HERNAEZ (State Bar No. 201441)	<b>,</b>
3	MATTHEW P VANDALI (State Bar No. 1060	62)
4	Email: vandall@kmm.com  KAUFF McCLAIN & McGUIRE LLP	PECETO I
5	One Post Street, Suite 2600 San Francisco, California 94104	
6	Telephone: (415) 421-3111 Facsimile: (415) 421-0938	MAY 3 0 2007
7	Attorneys for Defendants	RICHARD W. MIEKING CLERK, U.S. DISTRICT COURT
8	ALTA BATES SUMMIT MEDICAL CENTER, RUSSELL D. STANTEN, M.D., LEIGH I.G.	NORTHERN DISTRICT OF CAUFORM!
9	IVERSON, M.D., STEVEN A. STANTEN, M.D. WILLIAM M. ISENBERG, M.D., Ph.D.	., and
10	UNITED STATES D	ISTRICT COURT
11	NORTHERN DISTRIC	T OF CALIFORNIA
12		
13 -	COYNESS L. ENNIX, JR., M.D., as an	CASE NO. C 07-2486 WHA
14	individual and in his representative capacity under Business & Professions Code Section	DECLARATION OF WILLIAM M.
15	17200 et seq.,	ISENBERG, M.D., Ph.D. IN SUPPORT OF DEFENDANTS'
16	Plaintiff,	SPECIAL MOTION TO STRIKE PLAINTIFF'S COMPLAINT
17	V.	UNDER C.C.P. 425.16
18	RUSSELL D. STANTEN, M.D., LEIGH I.G. IVERSON, M.D., STEVEN A. STANTEN,	<b>DATE:</b> July 5, 2007 <b>TIME:</b> 8:00 a.m.
19	M.D., WILLIAM M. ISENBERG, M.D., Ph.D., ALTA BATES SUMMIT MEDICAL CENTER and does 1 through 100,	DEPT: Ctrm. 9, 19th Flr. JUDGE: Hon. William H. Alsup
20	Defendants.	COMPLAINT FILED: May 9, 2007
21	Doichdants.	TRIAL DATE: No date set
22		
23		
24		
25		
26		
27		

## I, William M. Isenberg, do hereby declare:

3

4

5

7 8

9

11 12

13

14

15 16

17

18

19 20

21

22

23

24

25

26

2728

KAUFF, MCCLAIN & MCGUIRE LLP ONE POST STREET SUITE 2600 SAN FRANCISCO, CA 94104 TELEPHONE (415) 421-3111

<ol> <li>I am a doctor holding a medical license in the State of California.</li> </ol>
From 1996 on, I have been an attending physician on one or both of the medical staffs of
Alta Bates Summit Medical Center ("Medical Center") [Summit from 1996 to the present;
Alta Bates from 1999 to the present]. I am and have been actively engaged in medical
staff governance and peer review as part of the Summit Medical Staff ("Medical Staff").
During the period from February 1, 2002 to present, I have served as an officer of the
Medical Staff, holding the following positions: Vice-President (2/2002 through 1/2004);
President (2/2004 through 1/2006); and Immediate Past President (2/2006 through the
present). I have been a member of the Medical Executive Committee ("MEC")
throughout such time by virtue of my officer positions, and prior to this as Chair of the
OB/Gyn Department. The duties of the MEC include evaluating the medical care
provided to Medical Center patients, organizing the Medical Staff's quality assurance
and peer review activities, initiating investigations into physician conduct that, among
other categories, appears reasonably likely to be detrimental to patient safety or to the
delivery of quality patient care, and taking or recommending to the Medical Center's
Board of Trustees corrective action, including the suspension or revocation of Medical
Staff membership and/or clinical privileges. I currently also serve as Vice Chair,
Department of OB/Gyn of the Summit Medical Center, a position that encompasses peer
review responsibilities for that department. I submit this declaration to provide
information regarding the peer review functions of the Summit Medical Staff in general,
and regarding the peer review issues occurring in 2004 through the present involving
Plaintiff Coyness Ennix, Jr., M.D., in particular. I have personal knowledge of the facts
contained in this declaration.

2. For several years before obtaining my medical degree, I worked as a research pathologist, and received my Ph.D. in Experimental Pathology from UCSF in 1987. From 1983 to 1991, I held various research positions with the UCSF Department of Pathology, including working as a Postdoctoral Fellow for the Gladstone Foundation

7

5

13

15

17

18

19

20

2122

23

24

25

2627

28

KAUFF, MCCLAIN
& MCGUIRE LLP
ONE POST STREET
SUITE 2600
SAN FRANCISCO. CA 94104

TELEPHONE (415) 421-3111

book chapters or abstracts addressing a variety of pathology research projects and issues. Many of these studies relied on statistical analysis in reaching conclusions.

3. Following my obtaining a Doctor of Medicine in 1992, I was a

Laboratories for Cardiovascular Research. I have co-authored some 40 manuscripts,

- resident in Obstetrics, Gynecology and Reproductive Sciences at UCSF. Upon the completion of my residency, I joined the Medical Staff at Summit Medical Center in the Department of OB/Gyn. I am Board certified in the field of Obstetrics and Gynecology. Since 1996, I have served as an ad hoc member of the UCSF Institutional Review Board and I am the course supervisor for the OB/Gyn module of the Physician Assistant degree program at Samuel Merritt College. I lecture medical students in pathology issues and conduct teaching rounds and small group teaching sessions for medical students in the Department of OB/Gyn.
- 4. I am not, and have never been, an employee of the Medical Center. Generally speaking, physicians are independent contractors admitted to the medical staffs of hospitals and subject to regulation and oversight by peer members of the medical staff. (The Summit Medical Staff also includes dentists, podiatrists and clinical psychologists.) Often, physicians are admitted to the medical staffs of a number of hospitals. Appointment, reappointment, the delineation of clinical privileges (areas of medicine in which the physician is authorized to provide clinical services), and the oversight of the quality of patient care services by Medical Staff members are conducted by the Medical Staff pursuant to Bylaws and Rules and Regulations. Bylaws and Rules and Regulations for the Summit Medical Staff have been in effect, as amended from time to time, throughout the time period covered by this lawsuit. All Medical Staff members, including Dr. Coyness Ennix, are subject to the provisions of both documents. The current Bylaws comprise some 80 pages; the current Rules and Regulations comprise an additional 67 pages. These documents delineate the structure under which the Summit Medical Staff engages in self-governance in cooperation with the Medical Center's Administration and its Board of Trustees. One of the principal functions of the

Kauff, McClain & McGuire LLP ONE POST STREET SUITE 2600 SAN FRANCISCO, CA 94104 ELEPHONE (415) 421-3111

Medical Staff is the conduct of peer review through which physicians' conduct and
patient care are evaluated and regulated, with the goal of monitoring the quality of health
care provided by all members authorized to perform clinical services at the Summit
campus of the Medical Center. The Medical Staff also has extensive documentation
requirements. These rules, as well as good medical practice, mandate that physicians
document all medical procedures they perform, and the evolution of the patient's hospita
stay, in a timely and thorough manner. The documentation requirements are to meet the
Medical Staff's own standards, as well as those set by a variety of state and national
accrediting bodies, such as the California Department of Health Services, the California
Medical Association's Institute of Medical Quality, the Centers for Medicare and
Medicaid Services, and the Joint Commission on Accreditation of Healthcare
Organizations. The Alta Bates campus has a separate Medical Staff organization. Many
physicians are members of both staffs. Since July 2003, both the Alta Bates and
Summit Medical Staffs have been parties to a memorandum of understanding providing
for the sharing of confidential peer review information concerning the professional
competence or conduct of physicians in whom the Staffs have a common credentialing,
recredentialing, quality improvement or peer review interest.

5. Attached hereto and incorporated herein by reference as Exhibit A are true and correct copies of the February 2003 Bylaws cover page, the table of contents, Article II ("Purposes and Responsibilities"), Section 3.4 ("Basic Responsibilities") of Medical Staff Membership"), Article VII ("Corrective Action"), Article VIII ("Interviews, Hearings and Appellate Reviews"), Article IX ("Officers"), Article X ("Clinical Departments and Services"), Article XI ("Committees"), and Article XIII ("Records and Proceedings of the Medical Staff"). The Bylaws are amended by action of the Medical Staff from time to time. Attached hereto as Exhibit B are true and correct copies of the above sections adopted effective June 2005. Attached hereto as Exhibit C are true and correct copies of the above sections in the currently effective Bylaws dated June 2006.

DECLARATION OF WILLIAM M. ISENBERG, M.D., PH.D. IN SUPPORT OF DEFENDANTS' SPECIAL MOTION TO STRIKE PLAINTIFF'S COMPLAINT UNDER C.C.P. 425.16

6.

9

6

13

12

14 15

16

17

18 19

20

21

22 23

24

25

26 27

28

KAUFF, MCCLAIN & MCGUIRE LLP ONE POST STREET SUITE 2600 SAN FRANCISCO, CA 94104 TELEPHONE (415) 421-3111

<ol><li>In late 2003/early 2004, in my capacity as incoming President of the</li></ol>
Medical Staff, I received information which ultimately led to an investigatory peer review
process concerning the quality of patient care being provided by Dr. Ennix relative to his
performance of a variety of cardiac surgeries, including bypass surgery (Coronary Artery
Bypass Grafting or "CABG"), aortic or mitral valve replacement and minimally invasive
valve surgeries (techniques which avoid opening the chest to perform valve replacement
surgery). While the peer review process is ongoing to the present time, this declaration
focuses on the time between early 2004 and beginning of 2006 (coinciding with my term
as President of the Medical Staff). There were many individuals involved in this process,
including doctors who performed the peer review, doctors who provided information to
the peer reviewers, Medical Center employees who provided information to the peer
reviewers, and Medical Center employees who assisted the Medical Staff in organizing
and documenting peer review meetings. Every aspect of the peer review process
concerning Dr. Ennix was conducted confidentially within the parameters of California
Evidence Code Section 1157. Doctors and Medical Center employees who provided
information were told of the confidential nature of the proceeding. Peer review
documents were marked "Confidential" and/or "Subject to Evidence Code 1157". To my
observation, the Medical Staff and the Medical Staff office personnel have been, and
remain, vigilant about protecting the confidentiality of the process as such is crucial to
the efficacy of the process, which requires that all involved answer inquiries in a totally
candid manner.

7. As mentioned above, many doctors have engaged in peer review of Dr. Ennix during the period of January 2004 to date, including members of the Cardiothoracic Surgery Peer Review Committee, members of the Surgery Peer Review Committee, members of the MEC, members of an Ad Hoc Committee ("AHC") appointed by the MEC in July 2004 pursuant to Section 7.1 (B) of the applicable Bylaws (Exhibit A), and the three outside physician reviewers retained by the AHC to review ten patient situations. The Medical Staff provided three formal reports to the 21-member Board of

1

6 7

9 10

8

12

13

11

14 15

16 17

18

19 20

21

22

23 24

25

26 27

28

KAUFF, McCLAIN MCGUIRE LLP ONE POST STREET SUITE 2600 SAN FRANCISCO, CA 94104

LEPHONE (415) 421-3111

Trustees of the Medical Center regarding this peer review process. The number of
individual doctors involved in some aspect of peer review of Dr. Ennix during the period
of 2004 to present exceeds 35. Additionally, the AHC considered an outside physician
review by Dr. Forest Junod of surgeries Dr. Ennix performed in 2002 at the Alta Bates
campus. Throughout the process, I, and others, consistently consulted with our Medical
Staff counsel, Harry Shulman, Esq. with the San Francisco office of Davis Wright
Tremaine, LLP.

8. I believe that I have been sued because I was President of the Medical Staff during a period of peer review of Dr. Ennix. The role I played in such process is required by the Medical Staff Bylaws and California law governing physician peer review. See, Section 9.2 of Exhibit A and Section 805 (b) of the California Business & Professions Code ("Section 805"). I have spent many uncompensated hours on not only this, but on many other peer review processes because I strongly believe that the confidential peer review system is an essential part of providing quality patient care to our community. My actions concerning Dr. Ennix's peer review were at all times undertaken for the exclusive purpose of fulfilling the Medical Staff's responsibility for the quality of patient care provided at the Medical Center. At no time did I act with any racially discriminatory or other non-peer review related motivation. I never observed anyone in the process acting for reasons other than fostering the quality of patient care. In each instance, my actions were taken in consultation with other Medical Staff officers, and were approved by the MEC. I am very concerned about the false accusations that Dr. Ennix has made against me and the other doctors he has sued, not only because they are untrue and disparaging but also because they will make (and have made) the task of obtaining Medical Staff participation in peer review activities exponentially more difficult. Even before the onset of this litigation, I had difficulty obtaining three members to serve on the AHC appointed to review Dr. Ennix's provision of patient care. Four doctors, including two African-Americans, declined my invitation to serve on the AHC. One individual, a former Medical Staff President, told me that his career had suffered

5

6

4

7 8

10

11

9

12 13

14 15

16 17

18

19

20

21

22

23

24 25

26

27

28

Kauff, McClain & McGuire LLP ONE POST STREET SUITE 2600 SAN FRANCISCO, CA 94104 TELEPHONE (415) 421-3111 from his being Chief of Staff and that he could not afford to have Dr. Ennix mobilize individuals against him. Taking time to conduct peer review is itself a burden on a doctor's practice; that burden is multiplied by threats of being sued or otherwise being involved in a litigation process.

There were three reasons for the inception of peer review activity concerning Dr. Ennix in early 2004: (a) a report (a true and correct copy of which is attached as Exhibit D) prepared by an outside physician reviewer, Dr. Forrest Junod, concerning surgeries performed by Dr. Ennix at the Alta Bates campus during 2002 (the Alta Bates Medical Staff provided this report to the Summit Medical Staff given the closure of the cardiac surgery program at Alta Bates, and pursuant to the Memorandum of Understanding between our two medical staffs regarding the sharing of peer review information that might impact the other campus); (b) the poor results of the first four minimally invasive valve procedures performed by Dr. Ennix at the Summit campus in late January/early February 2004 (excessive time in surgery, large blood usage, poor outcomes, including death, respiratory failure and a return to surgery); and (c) concerns expressed to Steven Stanten, M.D. (Chair of the Surgery Department and of the Surgery Peer Review Committee) or to me by anesthesiologists of both medical staffs. The Medical Staff officers placed a temporary moratorium on the performance of minimally invasive valve procedures following our being informed of the surgeries addressed in (b) above. Dr. Ennix agreed initially to a temporary, and himself suggested a permanent, moratorium on his performance of such procedures. Additionally, in March 2004, I reviewed a printout of the outcomes of Dr. Ennix's surgeries at the Summit campus from 2000 through February 2004 compared to the surgeries performed by members of his medical group as well as to all cardiothoracic surgeries performed at Summit for the same time period. In my judgment, that comparison supported the need for further peer review. Dr. Ennix's open heart surgeries at the Summit campus during that entire period had a mortality rate of 5.705% compared to all open heart surgeries performed during such period (a number which includes Dr. Ennix's procedures) which had a mortality rate

25

26

27 28

KAUFF, McClain & McGuire LLP ONE POST STREET SUITE 2600 SAN FRANCISCO, CA 94104 TELEPHONE (415) 421-3111

as Exhibit E.
15.385% for that two-month period. A true and correct copy of such printout is attached
alarming trend. Dr. Ennix's mortality rate after open heart surgeries increased to
for procedures performed by Dr. Ennix in January and February 2004 showed an
that number for all surgeons (inclusive of Dr. Ennix) was 4.787%. Additionally, the data
of 2.282%. Dr. Ennix's rate of a return to surgery after open heart surgery was 7.718%;

- 10. Following review by the Surgery Peer Review Committee (which included considering a report done by Dr. Hon Lee regarding the minimally invasive valve surgeries) and the expression of concern by that committee with regard to the conduct and documentation of the minimally invasive valve procedures, and in light of what the MEC officers believed was the need to review the Junod report, the MEC determined to convene the AHC. Attached as Exhibit F is a true and correct copy of my 4/21/04 letter to Dr. Ennix describing such decision. The applicable Bylaws state that "the MEC may undertake on its own to appoint an ad hoc investigative committee comprised of such individuals as it sees fit" (Section 7.1 (B) of Exhibit A). As noted above, Dr. Ennix agreed, voluntarily, to continue his moratorium on the performance of minimally invasive valve procedures initially until completion of the review process, and later on a permanent basis. Attached as Exhibit G is a true and correct copy of my letter to Dr. Ennix of April 28, 2004 which confirms Dr. Ennix's agreement to refrain permanently from performing these procedures. The officers of the MEC determined to lift the moratorium on other physicians' performance of minimally invasive valve procedures. The issues that arose in Dr. Ennix's performance of such procedures have not arisen when others have performed the procedures.
- 11. The Ad Hoc Committee, staffed in 2004 through April 2006 by Medical Staff members Lamont Paxton, M.D. (chair), Barry Horn, M.D. and Dat Ly, M.D., met on numerous occasions and interviewed several individuals. I have personal knowledge of this process as I attended AHC meetings. The methodology, conclusions and recommendations of the AHC are set forth in its 8/1/05 report which I understand will

Case 3:07-cv-02486-WHA

be presented to the Court as an attachment to Dr. Paxton's declaration. Part of the material considered by the Ad Hoc Committee was a review of ten patient hospital records (the four minimally invasive valve procedures from early 2004 and six bypass operations which resulted in death or substantial complications) by National Medical Audit ("NMA"), a unit of The Mercer Human Resource Consulting Group. The NMA report is attached as Appendix A to the AHC report submitted with Dr. Paxton's declaration. I made the decision to select NMA. I considered NMA's substantial years of experience in reviewing medical records for quality issues (over twenty years) and the nationwide reputations held by leaders of NMA. I was impressed, for example, by the credentials of one such leader, Arnold Milstein, M.D., M.P.H., who is widely recognized for his activities in improving healthcare programs. He is the co-founder of The Leapfrog Group for Patient Safety, an organization that works to improve hospital systems. Dr. Neil Smithline, NMA's Director of Clinical Quality, appointed two reviewers, Leland B. Housman, M.D., F.A.C.S., F.A.C.C., a cardiothoracic surgeon, and Robert H. Breyer, M.D., a cardiovascular surgeon. Attached as **Exhibit H** is a true and correct copy of a letter I sent to Dr. Ennix dated March 9, 2005 setting forth a procedure for him to speak with the reviewers, confirming that he had sent material for consideration by the reviewers, and forwarding to him the CV's of Drs. Breyer and Housman. Indicative of the care applied by the MEC to this peer review process is the fact that fees for this outside audit were about \$115,000, a number which includes charges for over 170 hours of time spent by the three physician reviewers on chart review, data analysis, consideration of material submitted by Dr. Ennix, speaking with Dr. Ennix, and preparation of the report. Dr. Ennix was given the opportunity to present written information, his perspectives on each case, and to answer questions from the NMA reviewers and the AHC members, prior to each of these bodies submitting their reports.

12. The NMA review was received by the Medical Staff Office on or about May 3, 2005. The NMA identified five instances of poor judgment (leading to death in three cases, post-operative cardiac arrest in one case, and severe

-8-

28

complications in another case); six instances of substandard technique; and many instances of "grossly substandard" operative notes. On May 10, 2005, acting pursuant to 7.2 (A) of then applicable Bylaws (Exhibit A) and following an interview with Dr. Ennix, officers of the MEC and the Chair of the Surgery Department, I made the decision to summarily suspend Dr. Ennix's clinical privileges based on my determination, as President of the Medical Staff, that failure to do so could result in an imminent danger to the health or safety of patients. Attached as **Exhibit I** is a true and correct copy of my letter to Dr. Ennix of May 11, 2005 explaining the basis for the summary suspension. which included the NMA report and the fact that Dr. Ennix had failed to document any physical examination of a post-operative patient (who had cardiac valve replacements) the day after the surgery (May 5, 2005). Dr. Ennix entered a note in the chart on May 6, but dated it May 5. I know this because two Medical Staff leaders (Dr. Fredric Herskowitz, then Vice President of the Medical Staff and Medical Director of the Intensive Care Unit, and Dr. Steven Stanten, Chair of the Surgery Department) saw the chart in the morning of May 6 without any doctor's note. Dr. Ennix thereafter entered a note, which he dated May 5, that however refers to lab values generated on May 6. While Dr. Ennix insisted that he saw the patient on May 5, there was no contemporaneous note that such was the case; the May 6 note does not describe an adequate physical examination for the first day after open heart surgery; and Dr. Ennix's description of the patient's condition on May 5 (in the May 6 note and during a May 10. 2005 discussion with officers of the MEC and the Chair of the Surgery Department) was inconsistent with the patient's actual condition as demonstrated in the patient's medical records. Taken together with the various problems in attending to patients disclosed in the NMA report (such as Dr. Ennix's leaving the hospital immediately following surgery so that he was not present when his patient had a cardiac arrest about eight minutes after leaving the OR), I determined that there was an imminent issue of patient safety.

13. As mandated in the Bylaws, I called an urgent executive session of the MEC on May 18, 2005 to consider whether to continue, modify, or lift the summary

27

2

3

4

5

6

7

8

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

suspension. Eleven of the fifteen physician members of the MEC were able to attend the meeting. In preparation for such meeting, all MEC members were provided with a copy of the NMA report, which was to be submitted to the AHC for review. One of the statistics that I presented to the MEC on May 18, 2005, in addition to discussing the circumstances of the May 6 chart notation and the NMA report, was the fact that Dr. Ennix had 28 cases fall out for peer review in the period of 2003 through April 2004 as compared to a mean of seven cases falling out for the other Summit cardiovascular surgeons during the same period. (The term "fall out "applies to peer review mandated by certain specified occurrences such as a patient death or a return to surgery. The fallout definitions are set by the Department, with MEC approval, and are applied uniformly to all members.) Dr. Ennix addressed the MEC regarding the summary suspension at the May 18, 2005 meeting. At the conclusion of the meeting, the MEC unanimously determined to uphold and continue the suspension pending the outcome of the AHC investigation. On May 19, 2005, in a telephone discussion with me, Dr. Ennix requested that he continue working at Summit Hospital in the restricted role of a surgical assistant. The MEC agreed to lift the summary suspension based on Dr. Ennix's self-suggested restriction until such time as the AHC and the MEC had finished their deliberations. Attached hereto and incorporated herein by reference as **Exhibit J** is a true and correct copy of my May 19, 2005 letter to Dr. Ennix confirming this voluntary restriction of privileges in place of an imposed suspension of all clinical privileges. Additionally, in April and May 2005, Dr. Ennix was repeatedly notified in writing by the Chair of the Medical Records Committee of the Medical Staff that his records were delinquent and incomplete. His staff privileges were temporarily suspended in accordance with usual Medical Staff procedure effective on or about May 24, 2005. This suspension was lifted after Dr. Ennix completed his outstanding records.

14. In its report dated August 1, 2005, the AHC recommended that Dr. Ennix's cardiothoracic surgery privileges be reinstated subject to proctoring in every phase of his patient care activities. This was a lesser step than the other option

identified of permanently restricting Dr. Ennix's privileges to surgical assisting. The AHC presented its 8/1/05 report to the MEC. The MEC scheduled to meet with Dr. Ennix on August 15, 2005, but when Dr. Ennix arrived, he informed the MEC that he was unprepared to discuss the issues at that time, and asked that the meeting be postponed. Therefore, the MEC met with Dr. Ennix on September 7, 2005 to discuss the AHC report. Following its 9/7/05 meeting with Dr. Ennix and after considering written information submitted on behalf of Dr. Ennix, the MEC determined on October 11, 2005 to reinstate Dr. Ennix's cardiothoracic surgery privileges subject to delineated proctoring requirements and subject to Dr. Ennix's attendance at a two day medical record-keeping course. Attached hereto and incorporated herein by reference as Exhibit K is a rue and correct copy of a letter I wrote to Dr. Ennix dated October 11, 2005 to communicate the action and reasoning of the MEC. My letter discusses the MEC's analysis of the AHC's recommendation and its consideration of written reports and testimonials submitted by Dr. Ennix. My 10/11/05 letter notes the conclusions of the AHC, as approved by the MEC, that those who wrote letters on Dr. Ennix's behalf did not appear to have substantial knowledge of the facts considered by the investigatory bodies. My letter further notes that Dr. Ennix had declined the request of the MEC to provide it with a description of the information presented by Dr. Ennix to the persons who wrote letters on his behalf.

15. As noted above, on two occasions Dr. Ennix voluntarily agreed to a restriction on his privileges to perform minimally invasive valve procedures, obviating any need for the MEC to consider taking action against those privileges which might have resulted in hearing rights under Article VIII of the Bylaws. Specifically, On April 16 2004, Dr. Ennix voluntarily agreed temporarily, and on April 26, 2004, he agreed permanently, to not perform minimally invasive valve procedures. These agreements were confirmed in letters to Dr. Ennix dated April 21, 2004 and April 28, 2004, respectively. (Exhibits F and G) Similarly, in May 2005, after Dr. Ennix's surgical privileges were summarily suspended based on the May 5 incident and the contents of the just-received NMA

25

26

27

Report, he requested that his privileges be restricted to surgical assisting, only, in lieu of the ongoing suspension. I had informed Dr. Ennix of his right to request a hearing under the Bylaws procedure to contest a summary suspension of fourteen days or more (Section 8.2 J of Exhibit A) On May 19, 2005, when Dr. Ennix requested restriction of his privileges to surgical assisting only, I told him that if the MEC accepted such request, the summary suspension would be lifted and he would forfeit his right to a hearing. Dr. Ennix told me that he understood such forfeiture. This 5/19/05 conversation is confirmed in Exhibit J. My letter of October 11, 2005 (Exhibit K) advises Dr. Ennix of his hearing rights under the Bylaws concerning the decision to impose proctoring requirements as delineated in that letter or thereafter modified by the MEC. Dr. Ennix did not request a hearing to challenge the proctoring requirements. Instead, Dr. Ennix agreed to the proctoring requirements set forth in the October 11, 2005 letter with one amendment (allowing the proctor not to be in the operating room during a limited portion of a surgical procedure). A true and correct copy of Dr. Ennix's letter of agreement dated October 24. 2005 is attached hereto and incorporated herein as Exhibit L. Therefore, with respect to all claims of improper treatment relative to his Medical Staff status and privileges, Dr. Ennix has not requested any hearing in accordance with Article VIII. Dr. Ennix has not. as required by Section 8.1 (B) of the Medical Staff Bylaws, exhausted the remedies required by the Bylaws as a precondition to legal action.

16. The proctoring restrictions were to be reviewed by the MEC at six month intervals. Additionally, normal peer review processes continued during the period after October 11, 2005. By letter dated December 30, 2005 (attached as **Exhibit M**), in my capacity as President of the Medical Staff and following consultation with Dr. Steven Stanten, Chair of the Surgery Department, and the three other officers of the MEC, I notified Dr. Ennix of a summary suspension of his surgery privileges in light of imminent concerns regarding patient safety. The December 30, 2005 letter notes that there were complications in five out of ten surgeries done since the reinstatement of privileges as indicated by those proctoring Dr. Ennix. Some of the proctors brought to my attention

21

22

23

24

25

26

these issues, which included Dr. Ennix's apparent difficulty with what the proctors told me should have been an uncomplicated procedure and that a patient's chest was closed at the end of a surgery, prior to Dr. Ennix's assuring that adequate control of bleeding had been accomplished. I talked with four of the proctors before bringing the concerns to the Medical Staff leadership as described above. On December 30, 2005 through January 2, 2006. Dr. Steven Stanten, with the assistance of Dr. Lamont Paxton. reviewed all surgeries performed by Dr. Ennix under the proctoring system during November-December 2005. A true and correct copy of the January 3, 2006 report by Dr. Steven Stanten is attached hereto as Exhibit N. Drs. Paxton and Stanten concluded that there had been very substantial improvement in Dr. Ennix's documentation, the protocols and surgical care appeared to be very adequate, and the suspension did not need to be continued. Based on Dr. Stanten's report, I notified Dr. Ennix by letter dated January 5, 2006 (Exhibit O is a true and correct copy of the 1/5/06 letter) of the lifting of the summary suspension. Because the suspension was less than fourteen days in duration, we were not required to file (and did not file) a report of the suspension with the state and federal oversight agencies described in Paragraph 18.

17. In April 2006, the AHC recommended a continuation of the proctoring until further evaluation to occur in three months based on the view that there was an inadequate number of cases to warrant a conclusion that the proctoring should be lifted. The MEC approved such recommendation. I participated in this process by virtue of my membership on the MEC as the Immediate Past President of the Medical Staff and my continued attendance at AHC meetings. Effective February 1, 2006, communications with Dr. Ennix on behalf of the MEC were from Dr. Fredric Herskowitz, who took over the President position at that time. In July 2006, The MEC, accepting a recommendation of the AHC, lifted the proctoring requirement and imposed a requirement that Dr. Ennix's cases be subject to retrospective chart review by the Chief of the Cardiothoracic Surgery Service or his designee. Attached hereto and incorporated herein by reference as **Exhibit P** is a true and correct copy of the July 11,

-13-

25

26

10

12 13

14

15

16 17

18

19

20

21

22

23

24

25

26

27 28

Kauff, McClain & McGuire LLP ONE POST STREET SUITE 2600 SAN FRANCISCO, CA 94104 TELEPHONE (415) 421-3111 19.

2006 letter sent by Dr. Herskowitz (with copies to those who had been performing proctoring functions and to the chair of the AHC). I am personally familiar with the contents of this letter through my membership in the MEC. This letter explains the determinations reached by the MEC in which I, along with several other MEC members, participated.

18. Throughout this process and upon the advice of counsel, I, in my capacity as President of the Medical Staff, provided reports to the Medical Board of California pursuant to Section 805 and to the federal National Practitioner Data Bank pursuant to the Health Care Quality Improvement Act regarding the following actions: (1) the April 2004 agreement by Dr. Ennix to restrict his privileges so as not to perform minimally invasive valve surgery; (2) the May 2005 summary suspension and Dr. Ennix's acceptance thereafter of voluntary restrictions on his privileges; and (3) the October 2005 reinstatement of cardiothoracic surgical privileges subject to proctoring restrictions. Both such oversight agencies were also notified of the lifting of the proctoring requirements in July 11, 2006. (A willful failure to file a report required by Section 805 is punishable by a fine not to exceed \$100,000 per violation. Section 805 (k)). Attached as Exhibit Q is a true and correct copy of a 7/13/06 letter received by Joanne Jellin, Director of the Summit Medical Staff, from the Medical Board of California regarding the 805 filings.

such, continues to be subject to peer review processes. As I remain a member of the

MEC. I am in a position to continue to have peer review responsibilities concerning Dr.

Ennix if issues arise regarding the quality of his patient care. Being sued in this lawsuit

makes me very reluctant to further participate in peer review of Dr. Ennix notwithstanding

my knowledge that the function is critical for patient safety. This lawsuit appears to me

to be a continuation of Dr. Ennix's pattern, exhibited throughout the peer review

described in this declaration, of seeking the intervention of persons or institutions

extraneous to the process for the apparent purpose of exerting pressure upon those

-14-

Dr. Ennix remains a member of the Summit Medical Staff and, as

1 engaged in the peer review to desist from effectuating our legal and ethical responsibilities for review and correction of poor patient care outcomes. For example: 2 3 Congresswoman Barbara Lee, The Sinkler-Miller Medical Association, and the NAACP all wrote letters of complaint about the peer review of Dr. Ennix to the Medical Center or 4 5 other corporate executives. I should note that, although all of the letters have exhibited 6 an exposure to only an inaccurate version of the facts, the Medical Staff and Medical 7 Center representatives have striven to maintain the confidentiality obligations that are 8 inherent to the integrity of the peer review process. This position, however, has made us regularly unable to respond substantively to these attempted interventions by third 9 10 parties, and has created significant awkwardness and tensions. I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct. Executed this 23<sup>rd</sup> day of May 2007, at San 12 13

Francisco, California.

WILLIAM M. ISENBERG, M.D., Ph.D.

115773.v1

18

11

14

15

16

17

19

20

21

22

23

24

25

26 27

28

KAUFF, McCLAIN & McGuire llp ONE POST STREET SUITE 2600 AN FRANCISCO, CA 94104 TELEPHONE (415) 421-3111

-15-